REMARKS

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested in view of the remarks herewith.

The October 2, 2003 Office Action called for restriction from among the following:

Group I. Claims 1, 4-17, 34, 39 are drawn to a parental artificial antigen presenting cell (AAPC) expressing b2-microglobulin and at least one exogenous accessory molecule. Classified in class 435, subclass 455;

Group II. Claims 2, 4-22, 34, 35, 39 are drawn to a parental artificial antigen presenting cell (AAPC) expressing b2-microglobulin, at least one exogenous accessory molecule, and a HLA molecule of a single type. Classified in class 435, subclass 455;

Group III. Claims 3-37, 40 are drawn to a parental artificial antigen presenting cell (AAPC) expressing b2-microglobulin, at least one exogenous accessory molecule, a HLA molecule of a single type, and at least one exogenous T cell-specific epitope. Classified in class 435, subclass 455;

Group IV. Claims 3-35, 38-40 are drawn to a parental artificial antigen presenting cell (AAPC) expressing b2-microglobulin, at least one exogenous accessory molecule, and a HLA molecule of a single type, and further comprising at least one exogenous T cell-specific epitope that is loaded to the AAPC. Classified in class 435, subclass 455;

Group V. Claims 41 and 42 are drawn to a method of activating cytotoxic T lymphocytes. Classified in class 435, subclass 375;

Group VI. Claims 43 and 44 are drawn to a composition comprising CTLs. Classified in class 435, subclass 325;

Group VII. Claim 45 is drawn to a method of treating a patient comprising administering to the patient the AAPC of group III or IV. Classified in class 424, subclass 93.21;

Group VIII. Claims 46 and 47 are drawn to a method of treating a patient comprising administering to the patient the CTLs of group VI. Classified in class 424, subclass 93.1;

Group IX. Claim 48 is drawn to a method of screening for accessory molecules using AAPCs of group III or IV. Classified in class 435, subclass 6 and 7.1;

Group X. Claims 49-53 are drawn to a method of screening for T cell-specific antigens using AAPCs of group II. Classified in class 435, subclass 6 and 7.1; and

Group XI. Claims 54-66 are drawn to a method of identifying antigen-specific CTLs using AAPCs of group III or IV. Classified in class 435, subclass 6 and 7.1.

Group III is elected, with traverse, for further prosecution in this application. Applicants reserve the right to file divisional applications to non-elected subject matter. Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

The application contains claims directed to an alleged patentably distinct species of AAPC defined by:

(1) a specific accessory molecule;

(2) the presence or absence of a HLA molecule of a single type; and

(3) the presence or absence of a HLA molecule of a specific T-cell specific epitope.

The species of AAPC defined by (1) the specific accessory molecule B7.1, (2) the presence of HLA molecule HLA A2.1 and (3) the presence of specific T-cell specific epitope E495 is elected, with traverse. Support for the recitation of B7.1 is on page 1, line 16 and page 14, lines 5-8 of the specification as originally filed; HLA A2.1 is on page 10, line 25 and page 14, line 10 of the specification as originally filed and E495 is on page 40, line 26 of the specification as originally filed. For search purposes, the Examiner is directed to the peptide synthesis section under Materials of Methods in Papanicolaou et al., Blood. 2003 Oct 1;102(7):2498-505. In the peptide synthesis section, the sequence for the HLA A2.1-restricted peptide that is derived from pp65 is NLVMVATV. Applicants note that the peptide is referred to as P495 in the Papnicolaou publication and submit that P495 is the same as E495 in the specification.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional inventions must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions." *Id.*

Groups I, II, III and IV are all classified in class 435, subclass 455. Therefore, the claims of Groups I, II, III and IV should be rejoined on the basis of classification.

It is respectfully submitted that any search for the parental AAPCs expressing b2-microglobulin and at least one exogenous accessory molecule, a HLA molecule of a single type, and at least one exogenous T cell-specific epitope of the Group III claims will certainly encompass references for the cells of the Group I, Group II, and Group IV claims, *i.e.*, parental AAPCs expressing b2-microglobulin and at least one exogenous accessory molecule (Group I), parental AAPCs expressing b2-microglobulin, at least one exogenous accessory molecule, and a HLA molecule of a single type (Group II), and AAPCs expressing b2-microglobulin, at least one exogenous accessory molecule, a HLA molecule of a single type, and further comprising at least one exogenous T cell-specific epitope that is loaded to the AAPC (group IV). These four groups are inextricably linked in that the all of the claims are drawn to parental AAPCs expressing b2-microglobulin and at least one exogenous accessory molecule. The parental AAPCs expressing b2-microglobulin, at least one exogenous accessory molecule, a HLA molecule of a single type, and at least one exogenous T cell-specific epitope (Group III) would require the same consideration as all parental AAPCs expressing b2-microglobulin and at least one exogenous accessory molecule (Groups I, II and IV). Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine Groups I-IV together, as a search for the Group III cells would necessarily include the cells of Groups I, II and IV.

Alternatively, it is respectfully submitted that any search for the parental AAPCs expressing b2-microglobulin and at least one exogenous accessory molecule, a HLA molecule of a single type, and at least one exogenous T cell-specific epitope of the Group III claims will certainly encompass references for the cells of the Group II, and Group IV claims, *i.e.*, parental AAPCs expressing b2-microglobulin, at least one exogenous accessory molecule, and a HLA molecule of a single type (Group II) and AAPCs expressing b2-microglobulin, at least one exogenous accessory molecule, a HLA molecule of a single type, and further comprising at least one exogenous T cell-specific epitope that is loaded to the AAPC (Group IV). These three groups are inextricably linked in that the all of the claims are drawn to parental AAPCs expressing b2-microglobulin, at least one exogenous accessory molecule, and a HLA molecule of a single type. The parental AAPCs expressing b2-microglobulin, at least one exogenous accessory molecule, a HLA molecule of a single type, and at least one exogenous T cell-specific epitope (Group III) would require the same consideration as all parental AAPCs expressing b2-microglobulin, at least one exogenous accessory molecule, and a HLA molecule of a single type

(Groups II and IV). Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine Groups II-IV together, as a search for the Group III cells would necessarily include the cells of Groups II and IV.

The Office Action States that Groups VII and III or IV are related as product and process use, and that since the process for using the product as claimed can be practiced with another materially different product (*i.e.*, the product of group III or IV could be used in a materially different process or the process of Group VII could be practiced with a materially different product), the Groups are distinct. Consequently, there is a relationship between the claims of Groups VII and III which would make any search and examination co-extensive.

In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested.

Furthermore, the Examiner is respectfully requested to review M.P.E.P. § 808.01(a), which states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

As evidence of no undue or serious burden in withdrawing entirely or reformulating the restriction requirement as herein requested, submitted herewith is a copy of pages of the International Search Report and International Preliminary Examination Report for PCT/US00/14668, of which this application is a national phase application. The attachments show that claims as herein pending had unity of Invention during International Prosecution, evincing that the restriction requirement should be reconsidered and withdrawn or reformulated as there cannot be any undue or serious burden in searching and examining all of the pending claims. These documents provide evidence of the holding of Unity of Invention made during International Prosecution (incorporated herein by reference) and the fact that there has already been a determination of Unity of Invention by the International Authority and a Search and examination based upon that determination, such that clearly there is no undue or serious burden on the Examiner in searching and examining all of the claims.

In the instant case, there is a disclosure of relationship between the claimed species. Applicants' claims are directed to, *inter alia*, parental AAPCs expressing b2-microglobulin and

at least one exogenous accessory molecule and methods for using these cells. The utility of the claimed AAPCs is to stimulate T cell production. The species merely relate to the specificity of the T cell response. Consequently, there is a disclosed relationship between the species.

Additionally, the claims are not broken into separate classifications on the basis of which species is claimed. Consequently, it can be assumed that the classification of all the claims into class 435, subclass 455 was made considering each of the species, such that the search of any species would be co-extensive and include the remaining species.

In view of the above, reconsideration and withdrawal of the election of species requirement are requested.

In summary, enforcing the present restriction and election requirements would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner, especially as the claims of all Groups have identical classifications. Furthermore, the election requirement has not been shown to be proper, especially since there are relationships among the species. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction and election of species requirement are respectfully requested.

CONCLUSION

In view of the remarks herein, reconsideration and withdrawal of the restriction requirement and election of species, are requested.

It is believed that no fees are occasioned by entry of this paper. However the Commissioner is hereby authorized to charge any additional fees, or credit any overpayment in fees, to Deposit Account 50-0320.

Early and favorable consideration of the application on the merits, and early Allowance of the application are earnestly solicited.

Respectfully submitted,
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